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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,668	12/18/2001	Stephen Griffin	1001.1535101	6574

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,668

Applicant(s)

GRIFFIN ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/16/05 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 4 and 20 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,944,701 to Dubrul.

In reference to claims 1 – 4 and 20 – 23, Dubrul discloses Applicant's claimed invention including an elongate core wire comprising a metal having an elastic limit; and a polymer jacket attached to and surrounding a distal portion of the core wire (Col. 3, lines 38 – 39; Col. 3, lines 62 – 64), the jacket comprising a shape memory polymer having an elastic limit, the polymer jacket being more stiff than the distal portion of the core wire which it surrounds such that if the tip is deformed into shape within the elastic limit of the metal and beyond the elastic limit of the polymer, the tip remains the shape (Col. 3, lines 35 – 39). Dubrul discloses the metal comprising a stainless steel, a super elastic metal and a nickel titanium alloy (Col. 2, lines 2 – 5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,701 to Dubrul in view of WO 01/07499 to Gunatillake et al.

In reference to claim 17, Dubrul discloses providing a guidewire comprising an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire and maintaining the polymer jacket and the portion of the core wire which it surrounds into a desired shape (Col. 3, lines 35 – 39). However, Dubrul fails to disclose heating the polymer to a temperature at or above glass transition temperature of the shape memory polymer and cooling the polymer to a temperature below the glass transition temperature of the shape memory polymer to maintain the shape. Gunatillake et al. teaches deforming a shape memory polymer, heating a shape memory polymer to a temperature at or above glass transition temperature of the polymer and cooling the polymer to a temperature below the glass transition temperature of the polymer to maintain the deformed shape of the polymer (Page 1, lines 11 – 22). It would have been obvious to one having ordinary skill in the art that in order to maintain the shape memory polymer jacket in the desired shape as disclosed by Dubrul, that one must deform the shape memory polymer, heat the shape memory polymer to a temperature at or above glass transition temperature of the polymer and cool the polymer to a temperature below the glass transition temperature of the polymer to maintain the desired deformed shape of the polymer (Page 1, lines 11 – 22).

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6. Claims 17 - 19 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,701 to Dubrul in view of U.S. Patent No. 5,662,621 to Lafontaine

In reference to claims 17 – 19, Dubrul discloses providing a guidewire comprising an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire and maintaining the polymer jacket and the portion of the core wire which it surrounds into a desire shape (Col. 3, lines 35 – 39). However, Dubrul fails to disclose heating the polymer to a temperature at or above glass transition temperature of the shape memory polymer and cooling the polymer to a temperature below the glass transition temperature of the shape memory polymer to maintain the shape. Dubrul also fails to disclose reheating and cooling the jacket to form and maintain different shapes including the original shape. Lafontaine teaches providing an elongate core wire with a shape memory polymer jacket surrounding a portion of the core wire; deforming the polymer jacket and the core wire into a shape; heating the deformed polymer jacket to a temperature at or above the glass transition temperature of the shape memory polymer (Col. 5, lines 49 – 56); and cooling the deformed jacket to a temperature below the glass transition temperature of the shape memory polymer to maintain the shape (Col. 5, lines 56 – 59). Lafontaine discloses reheating and cooling the jacket to form and maintain different shapes including the original shape (Col. 7, lines 24 – 34). It would have been obvious to modify the method as disclosed by Dubrul to include the steps of deforming the polymer jacket, heating the polymer jacket above or at glass transition of the polymer, cooling the deformed jacket to a temperature below the glass transition temperature and to repeat the steps to form and maintain different shapes including the original shape as taught by Lafontaine in order to navigate the guidewire through the tortuous paths of the vascular system.

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7. Claims 5 – 16 and 24 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,701 to Dubrul in view of U.S. Patent No. 6,485,458 to Takahashi.

In reference to claims 5 – 16 and 24 – 35, Dubrul discloses a shape memory polymer surrounding a portion of the core wire (Col. 3, lines 35 – 39), but fails to disclose the polymer being polyurethane, polynorbornene, polcaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of polunorbornene, styrene-butadiene, polyurethane, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Dubrul in that Takahashi teaches that shape memory polymers are interchangeable. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Lafontaine with any other shape memory polymer is a design consideration within the skill of the art.

Response to Arguments

8. Applicant's arguments filed 2/16/05 have been fully considered but they are not persuasive. Applicant asserts that the polymer as disclosed by Dubrul cannot be properly construed as a shape memory polymer. However, the Examiner disagrees. Applicant has given the example of a common electrical wire having a polymer coating that may be purchased in a coiled configuration, subsequently straightened during use, and bent into a curved configuration. The Examiner agrees

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that the polymer in the scenario as proposed would not be considered a shape memory polymer. However, a major difference between the polymer as disclosed by Dubrul and the polymer used for insulation on a common electrical wire is that the polymer as disclosed by Dubrul is responsible for maintaining the coiled shape (Col. 3, lines 37 – 39). Applicant points out that the shape memory alloy core disclosed by Dubrul must overcome the coil force of the polymer coating in order to allow the polymer to assume a straightened configuration. Hence, the polymer coating is forced from a coiled position to a straightened position. After removing the guidewire from the body, the guidewire again assumes a coiled configuration. The shape memory properties of the polymer as disclosed by Dubrul are unmistakable. The polymer returns to its original configuration (i.e. coiled) after being forced into another configuration (i.e. straight).

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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